

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/19/2009 has been entered.

Claim 7 has been added and claims 2 and 6 are cancelled. Claims 1, 3-5 and 7 remain pending.

The previous 112 1st Paragraph rejections have been withdrawn in light of applicant's submission made 08/19/2009.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3-5 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While there is support in the specification for a gel composition comprising protein or its hydrolysate, that does not coagulate at pH 3 to pH 4, being present at a level of 3 to 8 wt%, 5.5 wt% and 8 wt% (see for example Tables 3), the specification does not provide explicit support for a protein amount of 5.5-8 wt%.

5. Claims 1, 3-5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1 and 7, the phrase "reduced hard-to-digest dextrin" renders the claims indefinite because it is not clear what makes a hard-to-digest dextrin "reduced" or what compounds are encompassed by this phrase. With regards to the prior art, "reduced hard-to-digest dextrin" is encompassed by indigestible dextrin.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
9. Claims 1, 3-4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al. (WO 01/01789) in view of Emoto (US 6,458,395) and Ohkuma et al. (US 5,364,652).

Regarding claims 1, 4 and 7, Fuchs et al. disclose a gel composition comprising the following components and having a pH in the range of 3.5 to 4.1 (Abstract, P6/L1-2):

- | | |
|---------------------------------------|---|
| - Protein - i.e. whey protein isolate | about 1 to about 5 wt% (P3/L18-25, P8/Table, <i>see</i> protein proves about 1% to about 5% by weight of the nutritional composition-P4/L3) |
| -Calcium | 0.02-0.270 wt% (P5/Table) |
| -Acidulant | (P6/L2-5) |
| -Carbohydrate | 11-20 wt% (P8/Table) |
| -Fat | (P4/L22-23 – lipid source optional) |

- Water ~ 72-80 wt% (P6 – based on a solids content of 20-28% by weight)
- Juice 5-50 wt% fruit juice (P8/Table)

Fuchs et al. does not explicitly disclose that the protein does not coagulate at pH 3 to pH 4, a gel composition comprising agar and a gum including gellan gum or guar gum, that the acidulant is present in an amount of 0.5 -3 wt% or a masking component including hard-to-digest dextrin or reduced hard-to-digest dextrin.

Regarding coagulation, since the protein, whey protein isolate, disclosed by Fuchs is identical to that presently claimed, it is clear that it would intrinsically display the coagulation properties recited in the present claim.

Regarding acidulant, given that Fuchs et al. disclose a composition including acidulant and a pH identical to that presently claimed, it is clear that the amount of acidulant would inherently be in the range presently claimed.

Regarding gelling agents, Emoto teaches a nutritionally balanced gelatinous food product which is a composite gel formed with protein and about 0.2 to 5% of a gelling agent such as agar, guar gum or a combination thereof (Abstract, C5/L24-25). Emoto teaches that gelling agents have gelling and gel-stabilizing ability (C5/L26-28).

Fuchs et al. and Emoto are combinable because they are concerned with the same field of endeavor, namely, nutritionally supplemented protein gels. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added about a combination of agar and guar gum, as taught by Emoto, to the gel composition of Fuchs et al. to provide gel strength and stability to the gelatinous food product.

While Emoto teaches the addition of about 0.2 to about 5% of an agar and guar gum gelling agent combination, the reference does not explicitly disclose 0.1 to 1.0% agar and 0.05 to 0.3% guar gum. As gel texture is a variable that can be modified, among others, by adjusting the ratio of gelling agents, the precise concentration of agar and guar gum in the gelling agent combination would have been considered a result effective variable by one of ordinary skill in the art at the time of the invention. As such, without showing unexpected results, the claimed concentration of agar and guar gum in the gelling agent combination cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the concentration of agar and guar gum in the gelling agent combination of modified Fuchs et al. to obtain the desired texture characteristics (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

While Fuchs et al. disclose a gel composition comprising 5-50 wt% fruit juice (P8/Table), the reference does not disclose a gel composition comprising 0.1 to 20 wt% of a masking component including fruit juice and hard-to-digest dextrin or reduced hard-to-digest dextrin.

Ohkuma et al. teach food products comprising about 3.3% to about 52.5 % indigestible dextrin (Abstract, Examples 5-53) and that indigestible dextrin is a good source of dietary fiber (C1/L65-C2/L15). Ohkuma et al. teach that indigestible substances in the diet contribute to gastrointestinal health and reduced cholesterol (C2/L58-68).

Modified Fuchs et al. and Ohkuma et al. are combinable because they are concerned with the same field of endeavor, namely food products for nutritional supplementation. It would have

been obvious to one of ordinary skill in the art at the time of the invention to have included indigestible dextrin, as taught by Ohkuma et al., in the gel composition of modified Fuchs et al. for the purpose of making a product which contributes to gastrointestinal health and reduced cholesterol.

Regarding claim 3, Fuchs et al. disclose all of the claim limitations as set forth above. Further, Fuchs et al. disclose a gel composition further vitamin D in an amount of 0.25×10^{-6} to 0.625×10^{-6} wt% (P5/Table – where 1 IU of vitamin D = 0.025 µg).

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al. (WO 01/01789) in view of Emoto (US 6,458,395) as applied to claim 1, and further in view of Morris et al. (US 5,869,118).

Regarding claim 5, modified Fuchs et al. disclose all of the claim limitations as set forth above. While modified Fuchs et al. disclose a gel composition comprising a gelling agent combination of agar and guar gum, the references do not explicitly disclose gellan gum.

Morris et al. teach a liquid nutritional composition comprising 10 to 500 ppm gellan gum (0.001% to 0.05%) (Abstract, C4/L56-60). Morris et al. teach that the utilization of low concentrations of gellan gum results in the formation of a weak three dimensional network that effectively holds ingredients such as calcium, insoluble fiber and insoluble flavoring agents (C4/L24-38, C7/L22-29, Abstract). Morris et al. teach that gellan gum improves the physical stability of protein based nutritional compositions (C3/L60-67).

Modified Fuchs et al. and Morris et al. are combinable because they are concerned with the same field of endeavor, namely, protein-based nutritional products. It would have been

obvious to one of ordinary skill in the art at the time of the invention to have included gellan gum, as taught by Morris et al., in the gel composition of modified Fuchs et al. for the purpose of improving the physical stability of insoluble components.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-5 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-7 of copending Application No. 10/521,170. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the copending claims are drawn to a gel beverage composition while the present claims are drawn to a gel composition for protein and calcium supplementation, there is clear overlap between the present claims and the copending claims. Specifically, US appl. '170 claims a gel beverage composition having a pH of 3-4 and comprising protein which does not

coagulate at pH 3-4, agar, water, acidulant, fat, and saccharide. Further, US appl. '170 claims a protein material which does not coagulate at pH 3-4 selected from the group consisting of protein hydrolysate having a number average molecular weight of 500-10000, whey protein concentrate, whey protein isolate and desalted whey. US appl. '170 also claims a gel composition containing a gelling agent selected from the group consisting of gellan gum, carrageenan, pectin and gelatin.

US appl. '170 does not teach a gel composition comprising 0.1-0.5 wt% calcium, 0.1×10^{-6} to 10×10^{-6} wt % vitamin D, or 0.1 to 20 wt% masking agent.

Fuchs et al. (WO 01/01789) teach a gel composition comprising 0.02 – 0.270 wt% calcium (P5/Table), 0.25×10^{-6} to 0.625×10^{-6} wt% vitamin D (P5/Table – where 1 IU of vitamin D = 0.025 μ g) and 5-50 wt% fruit juice. Fuchs et al. teach that calcium and vitamin D are added to supplement the nutritional profile of the gel composition. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have added calcium, vitamin D and fruit juice, as taught by Fuchs et al., to the gel composition of US appl. '170 for the purpose of improving the nutritional and flavor quality of the gel composition.

Claims 1 and 3-5 directed to an invention not patentably distinct from claims 1-7 of commonly assigned US appl. '170. Specifically, although the conflicting claims are not identical, they are not patentably distinct for the reasons set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/521,170, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under

35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Response to Arguments

12. Applicant's arguments filed 08/19/2009 have been fully considered but they are not persuasive.

Applicants find that the composition of the present invention contains protein and calcium in high concentrations, but has a refreshing taste and is in the form of a soft gel suitable for eating and drinking. Applicants explain that "in order to achieve the excellent effects of the present invention, it is important to contain agar in an amount of 0.1-1 wt% in combination with guar gum or gellan gum in an amount of 0.05 to about 0.3 wt% as recited in the present claims." Applicants argue that the cited references do not teach or suggest these features of the present invention.

It is the Examiner's position that in combination, Fuchs and Emoto do teach the recited features of the present invention. Regarding gelling agents, Emoto teaches a nutritionally

balanced gelatinous food product which is a composite gel formed with protein and about 0.2 to 5% of a gelling agent such as agar, guar gum or a combination thereof (Abstract, C5/L24-25). Emoto teaches that gelling agents have gelling and gel-stabilizing ability (C5/L26-28).

Fuchs et al. and Emoto are combinable because they are concerned with the same field of endeavor, namely, nutritionally supplemented protein gels. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added about a combination of agar and guar gum, as taught by Emoto, to the gel composition of Fuchs et al. to provide gel strength and stability to the gelatinous food product.

While Emoto teaches the addition of about 0.2 to about 5% of an agar and guar gum gelling agent combination, the reference does not explicitly disclose 0.1 to 1.0% agar and 0.05 to 0.3% guar gum. As gel texture is a variable that can be modified, among others, by adjusting the ratio of gelling agents, the precise concentration of agar and guar gum in the gelling agent combination would have been considered a result effective variable by one of ordinary skill in the art at the time of the invention. I

Further, in response to applicant's argument that the references fail to show certain features of applicant's invention, as noted previously, the features upon which applicant relies (i.e., refreshing taste and soft gel suitable for eating and drinking) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants indicate that "when using generally used cation-reactive gelling agents such as gellan gum and carrageenan, it is difficult to gelate compositions containing high concentrations

of protein and calcium (see page 17, paragraph 3 of the specification).” Applicants find that there is “no mention or recognition of the problem in Fuchs of difficulty in gelation when such high concentrations of protein and calcium are employed.” Therefore, applicants argue, given Emoto does not employ calcium in a concentration range similar to that Fuchs or the present invention, there would have been no reason for one of ordinary skill in the art to expect the gelling agents disclosed by Emoto, used singly or in combination to be suitable for addressing the problems associated with compositions having a high concentration of calcium.

In response to applicant's argument that Emoto does not teach that a gelling agent comprising agar and guar gum would address the problems associated with compositions having a high concentration of calcium, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Further, given Emoto teaches gelling agents selected from the group consisting of pectin, furcelleran, carrageenan, agar, locust bean gum, guar gum and arabic gum or combinations thereof (C5/L22-27), it is clear that a combination of agar and guar gum is taught by Emoto. Further, given Emoto teaches a combination of agar and guar gum which is identical to the gelling agent presently claimed, it is clear that this particular combination would intrinsically be suitable for a gel composition comprising high concentrations of protein and calcium. Applicants have not demonstrated, with evidence in the form of data, that the agar and guar gum combination display an unexpected result over the remaining combinations of gelling agents taught by Emoto, i.e. agar and locust bean gum, agar and arabic gum, etc.

Applicants argue that while Fuchs discloses a gel composition comprising 2-4.5 wt% protein, based on p.8-9/Example 1, the gel composition of the same example comprising only 0.05 wt% calcium.

Applicants are directed to p.4-5 of Fuchs which discloses generally a gel composition comprising 1-5 wt% protein (p.4/L3) and 0.02-0.270 wt% of calcium (p.5/Table).

Applicants argue that Examiner's statements that "since Emoto teaches a combination of agar and guar gum which is identical to the gelling agent presently claimed, it is clear that this particular combination would intrinsically be suitable for a gel composition comprising high concentrations of protein and calcium" and "it is not suggested that the additional gelling agents taught by Emoto would be suitable for compositions comprising high levels of both calcium and protein" are based on improper hindsight reasoning. Applicants argue that there is no specific example in Emoto wherein a combination of agar and guar gum is employed.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

While Emoto does not teach a specific example wherein a combination of agar and guar gum are employed, given Emoto teaches gelling agents selected from the group consisting of pectin, furcelleran, carrageenan, agar, locust bean gum, guar gum and arabic gum or

combinations thereof (C5/L22-27), it is clear that a combination of agar and guar gum is taught by Emoto.

Applicants explain that a "variable must be recognized as contributing to a specific result before it can be acknowledged as prima facie obvious to determine the optimum or workable range of the variable." In this case, Applicants find that the cited references do not teach or suggest the advantageous effect of the specific combination of agar and guar gum or gellan gum and the amounts presently claimed.

It is well known in the art that the textural profile of a gel food composition can be optimized by adjusting the amounts and ratios of gelling agents. Therefore, given Emoto teaches a combination of gelling agents, including agar and guar gum, in a total amount identical to that presently claimed, since it is well known in the art the amounts and ratios of gelling agents can be optimized to obtain a desired texture profile, it would have been obvious to one of ordinary skill in the art at the time of the invention to have optimized the amount and ratio of agar and guar gum in the gel composition of modified Fuchs to obtain a desired texture profile.

Applicants note that the Examiner did not specifically address the limitation of the masking agent recited in claim 1 in the advisory action.

However, given the amendment submitted 06/22/2009 was not entered, the limitation of the masking agent was not of record and therefore not addressed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Friday; 7:30AM - 3:30PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./
Examiner, Art Unit 1794

/Keith D. Hendricks/
Supervisory Patent Examiner, Art Unit 1794